September 24, 2020

RE: CMS Proposed Prior Authorization Requirement for a Spinal Cord Stimulator Trials and Terms

To Whom It May Concern:

On behalf of the Ohio Society of Interventional Pain Physicians, we are writing this letter out of concern for the new CMS initiative to propose adding implantable spinal cord stimulator procedures to a short list requiring prior authorization based on increased utilization between 2007 and 2018. The 2021 CMS proposed rule for outpatient hospital procedures, if finalized, would mandate prior authorization as a requirement for spinal cord stimulators effective July 1, 2021.

As a physician based in Ohio, we are extremely concerned about this increased service burden and potential impediment to patient access. As you know, Ohio has been crippled by the opioid crisis. Opioid overdoses now exceed motor vehicle accidents as the most common cause of preventive death in the state of Ohio.

Spinal cord stimulation represents a technique that has been shown to decrease pain as well as decrease the utilization of opioid pain medications. It is a needed non-opioid therapy to treat pain in refractory chronic patients. By creating an additional prior authorization hurdle, it may decrease access to this therapy, which may have a negative impact on our citizens ability to maintain function, ADLs, and have a non-opioid treatment option.

We know that spinal cord stimulation has been shown to decrease opioid use post implant as noted by a study done by Adil et. al. in the Journal of Neurosurgery on August 31, 2020 in the article of "Impact of Spinal Cord Stimulation on Opioid Dose Reduction: A Nationwide Analysis" published in Neurosurgery.

We would also like to note that a successful spinal cord stimulator trial is needed prior to receiving a

permanent spinal cord stimulation, and only 65% of those who receive the trial actually get a permanent device. This trial period is a mechanism to prevent over-utilization of implantation of the device. These statistics were noted in the Journal Pain Physician published in 2020 by Odonkur et. al.

There is currently a national coverage designation for spinal cord stimulators that defines what is required to implant the device, including the failure of conservative care, trying alternatives first, as well as the successful psychological evaluation. These things are already being done prior to the trial and permanent implants. ***The addition of a prior authorization requirement reflecting what is already required in the national coverage designation simply represents an extra burden that will increase the cost of care for practicing physicians and hospitals who now have to do the duplicative work.*** As you know, if you look at the national coverage designation, NCD160.7, you can see that spinal cord stimulation therapy is reserved for patients who have failed other treatments and is considered a late last resort therapy.

As a result of the Coronavirus Pandemic, hospitals and physician practices are already under a significant strain financially and otherwise. Thus, it makes little sense to increase burdens further with a new regulatory requirement for which ultimate may decrease access to care. We are concerned that prior authorization would create an undue hurdle for providers/patients, while creating a barrier to non-opioid alternatives. The Coronavirus Pandemic has significantly changed and affected how hospitals, physicians, and patients manage medical care. Increasing the cost of care and stress on physician practices and hospitals while decreasing access to a therapy that is clinically beneficial, improves pain, function, and decreases opioids seems counterproductive to our citizens well-being who are under increased stressors due to COVID 19.

Requiring prior authorization for spinal cord stimulators is inconsistent with HHS, CDC, and FDA stated objective in national policies. For example, in 2012, the VA Opioid Safety Initiative, prescription opioid use in VA patients was reduced by 64% by the third quarter of 2020. The CDC Guidance on Opioid Use, the FDA Opioid Action Plan, and the fact that the opioid crisis was declared a national public health emergency under federal law all seem to indicate that physicians need to use alternatives to opioids to treat pain. However, trying to decrease access by increasing the service burden with additional prior authorization requirements seems inconsistent with the initiative to decrease opioids. This new prior authorization requirement may inadvertently steer patients to having to receive additional opioids.

This new policy may result in a delay in care because the prior authorization process will likely take some time which could further worsen patients' conditions.

Even without Coronavirus, we still strongly feel that this new requirement of requiring prior authorizations for spinal cord stimulator trials and permanent implants is not needed and may negatively impact our citizens from getting needed non-opioid based pain therapies.

The Ohio Society of Interventional Pain Physicians requests that CMS will suspend the initiative of requiring prior authorization requirements for spinal cord stimulator trials and permanent implants.

Sincerely,

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